Remarks

Claims 59-65 are pending after entry of this amendment. Claims 59, 64 and 65 are amended herein to more distinctly claim the invention. Claims 1-58 and 66-87 have been canceled. Support for these amendments can be found in the original claim language and throughout the specification, as set forth below. It is believed that these amendments add no new matter. In light of these amendments and the following remarks, applicants respectfully request reconsideration of this application, entry of these amendments and allowance of the claims to issue.

Applicants would like to thank Examiner Wilson for his courtesy and insights in the telephone interview with applicants on February 1, 2005. Pursuant to the telephone interview, applicants have amended independent claims 59, 64 and 65 by deleting problematic language and substituting therefor "native embryo" to make clear that the claimed egg indeed comprises an embryo that develops from the fertilization of an ovum inside the same shell that was deposited around the ovum as it passed through the reproductive tract of a female bird before the egg was oviposited (laid), the act of fertilization occurring after the unfertilized egg is oviposited. In other words, "native embryo" is limited to an embryo that develops in and hatches from the same shell in which the female pronucleus used to make the embryo was formed. Applicants believe that this clarification makes clear that the invention is patentable.

35 U.S.C. § 112, first paragraph

Claims 59-65 remain rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office Action alleges that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

While disagreeing with the basis of the rejection, pursuant to the interview, applicants amend claims 59, 64 and 65 herein to more clearly recite the relationship between the embryo and the shell that surrounds it. Specifically, the term "native embryo" was added in place of the deleted language. In the February 8, 2005 Interview Summary, the Examiner stated "to prevent

reinstating the 112/2nd rejection regarding 'native,' applicants must adequately argue the specification as originally filed would have allowed one of skill to conclude that i) the phrase 'native embryo' is limited to an embryo that develops and hatches in the same shell in which the female pronucleus used to make the embryo was formed and ii) the phrase 'native embryo' excludes embryos that have been removed from their shells and put into new shells in which they later are born."

"Compliance with the written description requirement is essentially a fact-based inquiry that will necessarily vary depending on the nature of the invention claimed." *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002). "The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d 1563-64 (Fed Cir. 1991).

A person of skill, after reading the instant application, would recognize that applicants were in possession of the claimed invention, *i.e.*, an oviposited avian egg from which a live chick can hatch, comprising a native embryo, wherein the embryo has fewer than 30,000 cells and can develop in the shell and hatch as a live chick. Applicants discovered that an unfertilized oviposited (laid) avian egg can be activated in the shell to produce a live chick. See in the specification page 7, lines 21-23. The gist of the application is (1) a method of activating, for example by fertilization, an unfertilized avian egg that has been oviposited (laid) from a bird's vagina, in order to produce a live chick (see in the specification page 8, lines 7-17); and (2) a developmentally early stage embryo in an oviposited avian egg from which a live chick can hatch. See in the specification page 12, lines 3-11. "Activation" means the initiation of embryo development in an unfertilized oviposited egg. See in the specification page 7, lines 15-16. Applicants teach that an avian egg comprises a hard, calcified shell at the time the egg is oviposited, and within the shell is a yolk that contains nutrients for supporting growth and development of an embryo. See in the specification page 7, lines 19-25. The instant application defines an embryo as a developing organism resulting from the joining of a female pronucleus and a male pronculeus during the process of egg fertilization. See in the specification page 8, lines 1-5.

A native embryo is an embryo that develops in the same shell which was deposited around a female pronucleus as it passed through the reproductive tract of the female before the egg is oviposited. See in the specification page 11, line 28 to page 12, line 1. Specifically, the specification states that "'native'" means growing, living or produced in its place of origin. Thus, a native embryo is an embryo that develops and hatches in the same shell in which the female pronucleus was formed." Thus, the embryo's place of origin is the shell in which the female pronucleus was formed. This definition of "native" is limited to embryos that develop in and hatch from the same shell in which the female pronucleus used to make the embryo was formed. By this definition, "native" does not include embryos that have been removed from their shells and put into new shells in which they later are born. Thus, the claim is clear and the rejection should be removed.

This definition of "native" is even more clear when viewed with the rest of the specification. Legally, it is clear that possession may also be shown by describing an actual reduction to practice of the claimed invention. "A specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose." *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998).

The examples describe methods for activating an oviposited unfertilized egg resulting in the claimed egg comprising a native embryo. Specifically, the examples describe various methods where eggs comprising a female pronucleus contained in their native shell are activated in the same shell in which the female pronucleus used to make the embryo was formed. The claimed egg is the result of the method described in the examples. See in the specification page 36, line 1 to page 39, line 4.

Thus, applicants describe the invention as it is claimed. Because the claimed invention was reduced to practice, applicants were in possession of the claimed invention at the time of filing of the application. Therefore, applicants respectfully request withdrawal of these rejections and allowance of amended claims 59, 64 and 65 and dependent claims 60-63.

35 U.S.C. § 112, second paragraph

Claims 59, 64 and 65 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office Action states that the claims are unclear because it is unclear whether the claims are listing steps required to use the "oviposited egg comprising an embryo and a shell" or steps required to make the egg.

Applicants respectfully traverse this rejection and believe it is rendered moot by the claims as amended. Claims 59, 64 and 65 are amended herein substituting language that more clearly defines the invention. Specifically, the addition of the term "native embryo" points out the relationship between the calcified shell and the embryo of the claimed invention. Applicants believe that these amendments overcome the rejections based on indefiniteness and respectfully request withdrawal of these rejections and allowance of amended claims 59, 64 and 65 and dependent claims 60-63.

35 U.S.C. § 102

Applicants acknowledge the withdrawal of the rejections of claims 59-65 based on lack of novelty. The Office Action acknowledges that "Johnston did not teach whether the embryo developed from the joining of the female pronucleus and the male pronucleus in the shell as claimed or outside of the shell after removing the ovum from the oviposited egg." See Office Action, sentence bridging pages 4 and 5.

35 U.S.C. § 103

Claims 59-65 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Johnston (1998, *Poultry Science*, Vol. 77, page 142), in view of Goldberg (1992, *Ped. Research*, Vol. 32, pages 23-26). Specifically, the Office Action states that Johnston teaches an oviposited egg comprising an embryo and a shell. The Office Action goes on to state that sperm was injected into the ovum after the egg was oviposited; therefore, the shell was deposited around the female pronucleus before the female and male pronucleus were joined as claimed. The Office Action states that the fertilized oocyte is a zygote or embryo; the zygote is one cell, which is less

than 10,000 cells as claimed. The Office Action goes on to state that the embryo can develop in the shell and hatch as a live chick because Johnston teaches that the embryo showed signs of cellular proliferation. However, the Office Action acknowledges that Johnston does not teach the embryo developed from the joining of the female pronucleus and the male pronucleus (fertilization) in the shell as claimed.

The Office Action states that Goldberg teaches a 1mm window in avian eggs having embryos to inject various solutions. The Office Action then states that it would have been obvious to one of skill in the art at the time the invention was made to "inject sperm into an oviposited avian egg having less than 10,000 cells as taught by Johnston by making a 1 mm window in the egg as taught by Goldberg. This would have resulted in the joining of the male and female pronuclei in the shell as claimed."

Further, the Office Action denies applicants' assertion that in Johnston, the ovum was removed from the shell prior to fertilization. The Office Action goes on to state that the combined teachings of Johnston and Goldberg do not require removal of the ovum from its shell. The Office Action alleges that the egg taught by Johnston is capable of hatching.

Claims 59, 64 and 65 are similarly amended herein to more distinctly define the invention. For example, amended claim 59 recites "an oviposited avian egg from which a live chick can hatch, comprising a native embryo, wherein the embryo has fewer than 30,000 cells and can develop in the shell and hatch as a live chick." In view of these proposed amendments and the associated discussion in the interview, this issue seemed to be resolved. Nevertheless, applicants recite their arguments below for the sake of clarity on these issues.

The U.S. Patent and Trademark Office has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. See *In re Warner et al.*, 379 F.2d 1011, 154 U.S.P.Q. 173, 177 (C.C.P.A. 1967); *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598-99 (Fed. Cir. 1988). "It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." *Id.* Moreover, in rejecting a claim under 35 U.S.C. § 103, the Examiner must establish a *prima facie* case that: (i) the prior art suggests the claimed invention; and (ii) the prior art indicates that the invention would have a reasonable

likelihood of success. See *In re Dow Chemical Company*, 837 F.2d 469, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988). In order for a reference to be effective prior art under 35 U.S.C. § 103, it must provide a motivation whereby one of ordinary skill in the art would be led to do that which the appellant has done. See *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1535, 218 USPQ 871, 876 (Fed. Cir. 1983). "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988). "When the references cited by the examiner fail to establish a *prima facie* case of obviousness, the rejection is improper and will be overturned." *In re Deuel*, 51 F.3d 1552, 1557, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995) (citing *Fine*, 837 F.2d at 1074).

The Office Action alleges that the suggestion to combine prior art teachings can be found in the cited references. However, the present rejection does not find the required suggestion in either source. Nowhere has it been shown or argued that those of ordinary skill in the art had any general knowledge relevant to activating, for example by fertilization, an unfertilized oviposited (laid) avian egg from which a live chick can hatch, comprising a native embryo, wherein the embryo has fewer than 30,000 cells and can develop in the shell and hatch as a live chick. Instead, the rejection points to a motivation to achieve the result accomplished by applicants.

Johnston ("In Vitro Sperm Binding, Penetration, and Fertilization of Recently Oviposited Chicken Eggs," Thesis, Graduate School of Clemson University, December, 1998) (Reference "AM," cited in Form PTO 1449 of the Information Disclosure Statement) corresponds to and elaborates on the cited abstract. Johnston teaches the fertilization of an ovum only after it has been removed from the shell. Johnston also teaches that the ovum after removal from the shell, was treated by mild hydrolysis of the OPL with 0.01 N HCl. Further, Johnston teaches that the *in vitro* fertilized oocytes were subsequently cultured in a medium of thin egg albumen and sterile PBS. Therefore, Johnston creates a very different composition of matter than claimed by applicants.

The Office Action is wrong when it alleges that "Johnston does not teach the ovum was removed from the shell prior to fertilization. Moreover, the combined teachings of Johnston and Goldberg do not require removal of the ovum from its shell." See Office Action, page 6, third paragraph. Moreover, this allegation is inconsistent with the Office Action's acknowledgment

that "Johnston did not teach whether the embryo developed from the joining of the female pronucleus and the male pronucleus in the shell as claimed or outside of the shell after removing the ovum from the oviposited egg." See Office Action, sentence bridging pages 4 and 5.

The Office Action ignores the term "*in vitro*" which means "in glass." Johnston teaches adding sperm to an ovum in a glass dish, after the ovum has been removed from an oviposited egg. Johnston does not teach an oviposited avian egg from which a live chick can hatch, comprising a native embryo, wherein the embryo has fewer than 30,000 cells and can develop in the shell and hatch as a live chick. Instead, Johnston created a complicated composition of matter comprising an *in vitro* fertilized ovum, removed from the shell, that was treated by mild hydrolysis of the OPL with 0.01 N HCl and cultured *in vitro* in medium of thin egg albumen and sterile PBS. The Johnston method only alleges fertilization of an ovum that was removed from the shell and cultured *in vitro*. In contrast, applicants have created a simpler and more natural composition of matter by keeping basically intact the shell deposited around the unfertilized ovum before oviposition and then producing a native embryo by injecting sperm through the shell to fertilize the ovum inside the shell. See in the specification page 8, lines 7-25.

The pending claims also require that the embryo has fewer than 30,000 cells and can develop in the shell and hatch as a live chick. The Office Action states that the embryos created by Johnston can hatch as a live chick. This conclusion is not supported by any of the art cited in the Office Action. The art cited in the Office Action specifically does not support this notion since Johnston, as is clear from the Johnston Thesis, was only able to create very early *in vitro* embryos when the goal was to create and develop avian embryos. Indeed, the Johnston abstract states "[w]e are developing a system to *in vitro* fertilize, and develop avian embryos from recently oviposited eggs" (emphasis added). The Johnston abstract and the Johnston Thesis on pages 39-43 and Table 3 show that Johnston was only able to create very early embryos that ceased to develop. This is in contrast to applicants' claimed invention where the embryos

develop in the shell and hatch as a live chick. Thus, Johnston's goal was to produce developed avian embryos. Because Johnston failed, they actually teach away from applicants' successful invention.

Goldberg is a reference related to the study of cardiac teratogenicity of dichloroethylene in a chick model. Goldberg discloses something completely different from the claimed invention. This reference does not teach, suggest or motivate a person of skill to activate an oviposited, unfertilized avian egg in a shell to produce an early developmental embryo with a reasonable expectation of success. In fact, the reference does not mention sperm or other means of activation at all. Thus, Goldberg adds nothing to cure the deficiencies of Johnston.

There is no scientific basis for the Office Action's allegation that a person of skill at the time of the invention would be motivated to "inject sperm into an oviposited avian egg having less than 10,000 cells as taught by Johnston by making a 1 mm window in the egg as taught by Goldberg. This would have resulted in the joining of the male and female pronuclei in the shell as claimed." See Office Action, page 6, second paragraph. No person of skill in the art would be motivated to inject sperm into an oviposited egg that had already been fertilized and contained an embryo containing fewer than 10,000 cells. An oviposited egg containing an embryo that has fewer than 10,000 cells is a fertilized egg. Therefore, such an injection, as described in the Office Action, would not have any useful purpose and could only cause damage to the developing avian embryo.

Further, the allegation that the claimed invention is obvious over Johnston and Goldberg is incorrect because any motivation to achieve applicants' results relies on impermissible hindsight. That is, it is all too easy to discover reasons why those in the art would have wanted to achieve applicants' results after the fact. The current rejections are analogous to the rejection deemed improper in *In re Deuel*, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). In this case, the court reaffirmed that a rejection based on an "obvious to try" standard was improper.

Neither Johnston nor Goldberg, alone or in combination, suggests producing an oviposited avian egg from which a live chick can hatch, comprising a native embryo, wherein the embryo has fewer than 30,000 cells and can develop in the shell and hatch as a live chick. Only with the knowledge of the present invention and impermissible hindsight can a rejection of claims 59-65 be made on the basis of obviousness. Thus, the Office Action fails to make a *prima facie* case for obviousness; therefore, these rejections are improper and should be withdrawn.

Applicants have created an innovative composition of matter, *i.e.*, a developmentally early native avian embryo, that was desired but not accomplished or suggested by the art. Indeed, the claimed novel composition is efficiently derived and is the result of an efficient breeding method that can revolutionize poultry breeding processes. Moreover, the large number of early embryos in their respective shells that can be produced by the methods associated with the claimed invention can be utilized for high throughput transgenesis. In other words, the compositions of this invention can be created in large numbers and, thus, can be engineered in large numbers to produce a desired transgenic bird. Thus, the invention provides major advantages to the poultry industry that were desired but unobtainable from prior art methods. Applicants, therefore, respectfully request that these rejections be withdrawn and that amended claims 59, 64 and 65 and dependent claims 60-63 be allowed.

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending claims are believed to be warranted, and such action is respectfully requested. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issuance.

A Credit Card Payment Form PTO-2038 authorizing payment in the amount of $60.00 for a one (1) month extension of time fee and a Request for Extension of Time are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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